

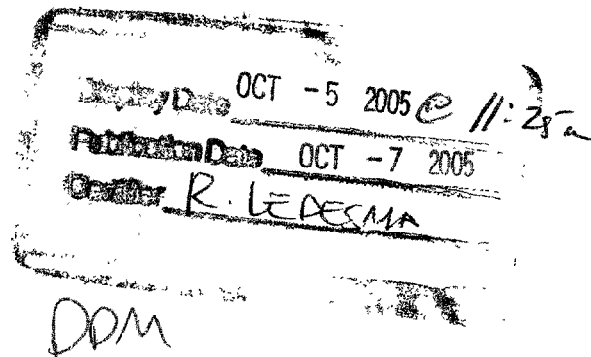
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.



This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services (HHS), when that research is also regulated by FDA.

Date and Time: The meeting will be held on Wednesday, November 16, 2005, from 8 a.m. to 6 p.m., and Thursday, November 17, 2005, from 8 a.m. to 5 p.m.

Location: Washington DC North/Gaithersburg Hilton, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Jan N. Johannessen, Office of Science and Health Coordination of the Office of the Commissioner (HF-33), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, rm. 14C-06) Rockville, MD 20857, 301-827-6687, or by e-mail: jjohannessen@fda.gov or oc05241

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FDA Advisory Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 8732310001. Please call the Information Line for up to date information on this meeting.

Agenda: On Wednesday, November 16, 2005, the committee will hear and discuss the recommendation of the Pediatric Ethics Subcommittee from its meeting on November 15, 2005, regarding a referral by an Institution Review Board of a proposed clinical investigation involving children as subjects that is regulated by FDA and is conducted or supported by the Department of Health and Human Services. The committee will also discuss pediatric obesity and clinical trial designs for the evaluation of devices intended to treat pediatric obesity.

On Thursday, November 17, 2005, the committee will continue its discussion of clinical trial designs for, and ethical issues related to, the evaluation of devices intended to treat pediatric obesity.

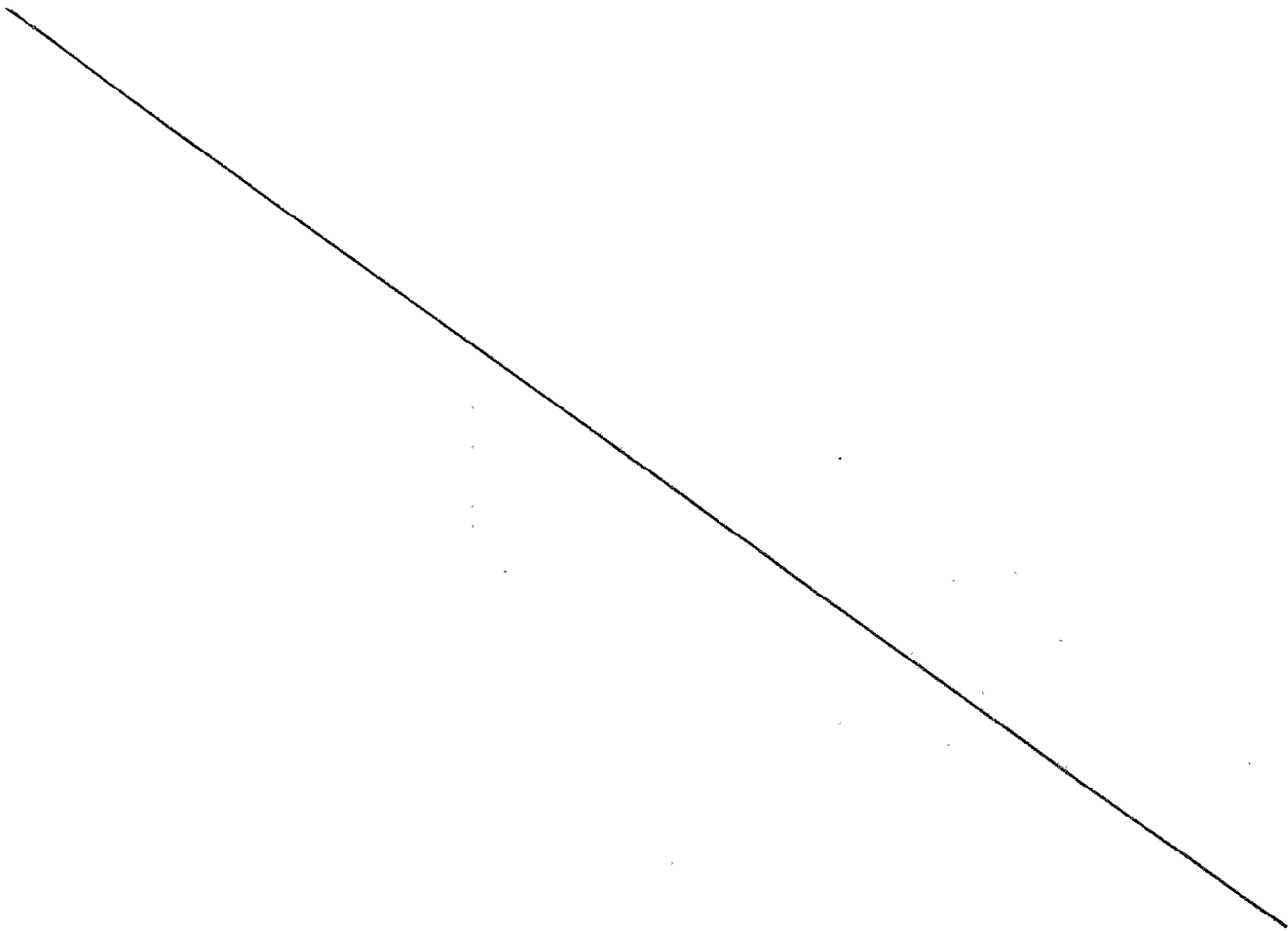
The background material will become available no later than the day before the meeting and will be posted under the Pediatric Advisory Committee (PAC) Docket site at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>. (Click on the year 2005 and scroll down to Pediatric Advisory Committee meetings.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by November 4, 2005. Oral presentations from the public will be scheduled on Wednesday, November 16, 2005 between approximately 1:30 p.m. and 2:30 p.m. and Thursday, November 17, 2005, between approximately 9:15 a.m. and 10:15 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by November 4, 2005, and

submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

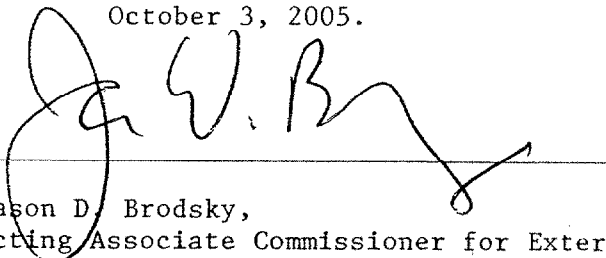
Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please notify Jan Johannessen at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act
(5 U.S.C. app. 2).

Dated: 10-3-05
October 3, 2005.


Jason D. Brodsky,
Acting Associate Commissioner for External Relations.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

